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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,830

04/14/2006

Mikhail Vladimirovich Kutushov

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EXAMINER

WALCK, BRIAN D

ART UNIT

PAPER NUMBER

4181

MAIL DATE

DELIVERY MODE

10/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/575,830

Applicant(s)

KUTUSHOV, MIKHAIL
VLADIMIROVICH

Examiner

Brian Walck

Art Unit

4181

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/2007</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Abstract

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it contains 255 words, which is more than the acceptable limit of 150 words. Additionally, the abstract states "plane ranges from 500-5000 \square m and the thickness is equal to 0.1-1000 \square m." \square m should be changed to μ m in both instances.

Specification

3. "Dextran" is consistently misspelled as "dextrans" throughout the specification. Appropriate correction is required.
4. "mc" is consistently used to represent the term "micrometer." " μ m" should be used instead.
5. The use of the trademark SEPHADEX® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

6. The claims are objected to because of the following minor informalities:
- a. In claims 3, 4, 8, 10, 17, 18, 22, and 24, "dextran" is misspelled as "dextrans".
 - b. Claim 1 states "mc" instead of " μm "
 - c. Claims 6 and 20 state " $^{\circ}\text{K}$ " instead of " $^{\circ}\text{K}$ "
 - d. Claims 6 and 20 state "MmHg" instead of "mmHg"
 - e. Claims 6 and 20 state " Vt/cm^2 " instead of " W/cm^2 "
 - f. Claims 16 and 30 state " Vt/cm " instead of " W/cm^2 "

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "the core made in a form of a flake with dimensions in a plane of (500-5000) mc and with a thickness of (0.1-1000) mc." The term "flake" is not explicitly defined in the specifications or the claims, but seems to imply an object with a plane width greater than its thickness. However,

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the claimed limitations on the dimensions encompass particles with a thickness greater than or equal to their plane width (in the range between 500 and 1000 μm). Claims 2-30 are likewise rejected as they are dependent on claim 1 and are subject to the same indefiniteness.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Russian Patent No. 2178313 to Kutushov. Page 1, paragraph [0006] of the specification of the instant application states that Russian Patent No. 2178313 to Kutushov discloses;

"[a] ferreed sorbent (FS), with the atomic centre or core as grading fraction with particle size of (0.1-1000) mc, made of iron, iron oxides, nickel, or iron-nickel alloy, and coated with a single or double layer coat of carbon, aluminum oxide, silicon dioxide, zirconium dioxide, dextrane, e.g. sephadex, gelatin, albumin, polysaccharide, e.g. amylum, or ion-exchange resins, e.g. cations or anions, where the coat upper layer is either conjugated with antibodies, or modified by pharmaceutical composition, e.g. antibiotics or phthalhydrazide salines, e.g. 5-amino-2,3-dihydro-1,4-dione salines or else fermented e.g. with urease."

Comment [j1]: Need to explain who teaches this quotation and cite where you get it from.

11. Claim 1 of the instant application recites the limitations;

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“1. A ferreed sorbent having a ferromagnetic core, with one of a single layer coat, a double layer coat and no coat, comprising: the core made in a form of a flake with dimensions in a plane of (500-5000) mc and with a thickness of (0.1-1000) mc.”

RU 2178313 to Kutushov anticipates the “a ferreed sorbent having a ferromagnetic core” limitation of instant claim 1 because RU 2178313 to Kutushov discloses a “ferreed sorbent (FS), with the atomic centre or core... made of iron, iron oxides, nickel, or iron-nickel alloy.” These materials are all inherently ferromagnetic.

RU 2178313 to Kutushov explicitly anticipates the “with one of a single layer coat, a double layer coat, and no coat” limitation of instant claim 1.

RU 2178313 to Kutushov anticipates the “the core made in a form of a flake with dimensions in a plane of (500-5000) mc and with a thickness of (0.1-1000) mc” limitation of instant claim 1 because Kutushov discloses “the atomic centre or core as grading fraction with particle size of (0.1-1000) mc.” The instant application does not explicitly define the term “flake” in the specification or the claims. Thus, the dimensional limitations of instant claim 1 include particles with equal plane width and thickness with a size between 500 μm and 1000 μm , which is anticipated by RU 2178313 to Kutushov.

12. The further limitations of instant claims 2-5 and 17-19 are explicitly anticipated by RU 2178313 to Kutushov's disclosure of:

“[a] ferreed sorbent (FS), with the atomic centre or core... made of iron, iron oxides, nickel, or iron-nickel alloy, and coated with a single or double layer coat of carbon, aluminum oxide, silicon dioxide, zirconium dioxide,

dextrane, e.g. sephadex, gelatin, albumin, polysaccharide, e.g. amylum, or ion-exchange resins, e.g. cations or anions, where the coat upper layer is either conjugated with antibodies, or modified by pharmaceutical composition, e.g. antibiotics or phthalhydrazide salines, e.g. 5-amino-2,3-dihydro-1,4-dione salines or else fermented e.g. with urease”

13. With respect to instant claims 6-16 and 20-30, the instant claims are product by process claims referencing the product claimed in claim 1. MPEP §2113 states:

“Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps”

Comment [j2]: caps?

Since the steps recited by claims 6-16 and 20-30 do not imply any further structural limitations on claim 1, claims 6-16 and 20-30 are rejected for the same reasons as claim 1.

14. Claims 1-30 are also rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5980479 to Kutushov. The specifications of US 5980479 to Kutushov, column 5 line 42 to column 6 line 22, discloses:

“[A] biocompatible magneto-conductive material is in the form of paramagnetic or ferromagnetic particles... The particles are formed of one of the following materials: iron in its reduced form, so-called `ferrum reductum`; iron oxide; carbon coated iron; dextran coated iron, silicone coated iron, aluminum coated iron...The particles of either kind are, then, specifically processed so as to have swelled, activated surfaces for possessing the following properties: high adsorption capability...

...

Moreover, the particle is of substantially small size about 0.01 μm to 1 mm...

...

Optionally, the particles may be further coated by a protective coating formed of either protein of any known kind, particularly a food protein, or the patient's blood, so-called 'auto-blood'. Alternatively, or additionally, the particles may be coated by a selective coating, for example antibody, depending on a preselected pathogenic agent to be removed from the biological fluid. Moreover, the paramagnetic particle either coated or not may be further modified by antibiotics or similar medical compounds."

15. With respect to claims 1-3 and 17 of the instant application, US 5980479 to Kutushov discloses "ferromagnetic particles... formed of one of the following materials: iron in its reduced form, so-called 'ferrum reductum'; iron oxide; carbon coated iron; dextran coated iron, silicone coated iron, aluminum coated iron... possessing... high adsorption capability... Moreover, the particle is of substantially small size about 0.01 μm to 1 mm." This anticipates the limitations of instant claims 1-3, 17 for particles with equal plane width and thickness with a size between 500 μm and 1000 μm .

16. With respect to instant claims 4 and 18, US 5980479 to Kutushov discloses "the particles may be further coated by a protective coating formed of... protein of any known kind..." Since albumin is a "protein of any known kind," this disclosure anticipates the outer layer coat of albumin limitation of instant claims 4 and 18.

17. With respect to instant claims 5 and 19, US 5980479 to Kutushov discloses “the paramagnetic particle either coated or not may be further modified by antibiotics or similar medical compounds.” This anticipates the conjugation with antibiotics limitation of instant claims 5 and 19.

18. With respect to instant claims 6-16 and 20-30, the instant claims are product by process claims referencing the product claimed in claim 1. MPEP §2113 states:

“Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps”

Comment [j3]: caps?

19. Since the steps recited by claims 6-16 and 20-30 do not imply any further structural limitations on claim 1, claims 6-16 and 20-30 are rejected for the same reasons as claim 1.

20. Claims 1 and 2 are also rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3419901 to Nordhlom. The first line of the abstract of US 3419901 to Nordhlom, discloses a method for producing “small flakes of metallic nickel, about 1/16 inch square and about 0.000040 inch thick.”

21. Nordhlom anticipates the limitations of instant claim 1 because the nickel flakes have no coat and are inherently ferromagnetic, and the dimensions are “about 1/16 inch square and about 0.000040 inch thick,” or about 1587.5 μm square and about 1.016 μm thick, which falls within the instant claim 1 limitations of “dimensions in a plane of (500-5000) mc and with a thickness of (0.1-1000) mc.”

22. With respect to claim 2, Nordhlom explicitly discloses a nickel core.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Walck whose telephone number is (571)270-5905. The examiner can normally be reached on Monday-Friday 8 AM-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Walck
October 1, 2008

/Stuart Hendrickson/
Primary Examiner, Art Unit 1793